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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/847,010	05/01/2001	Perry A. Frey	032026-0476D	5359

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Mark A. Kassel
Foley & Lardner
150 E. Gilman Street
P.O. Box 1497
Madison, WI 53701-1497

EXAMINER

HUTSON, RICHARD G

ART UNIT

PAPER NUMBER

1652

9

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/847,010

Applicant(s)

FREY ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-32 and 36-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29,30,32 and 37-45 is/are rejected.
- 7) ☒ Claim(s) 31,36 and 46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group B, SEQ ID NOs: 3 and 4, Paper No. 8, 12/2/2002 is acknowledged. Applicants traverse the restriction requirement between the eight different polynucleotide sequences and their encoded polypeptide sequences on the basis that inventions (A)-(H) are closely related and the search and examination of inventions (A)-(H) would not be a serious burden for the Examiner. Applicants further assert that a serious burden maybe prima facie demonstrated if the examiner shows by appropriate explanation either separate classification, separate status in the art or a different field of search for the different groups. Applicants argument is not found persuasive because while each of the inventions share the same classification, each of the inventions (A)-(H) require a different field of search. Each of the polynucleotide and their encoded polypeptide sequences are structurally different molecules from different species of organisms. Thus the examination of each of these inventions would involve the search of their common activity, lysine 2,3-aminomutase, as well as their different chemical structures, employing both sequence databases as well as text search strategies. These would involve searches based on each of the different structures as well as the different sources of the polynucleotide and polypeptide sequences. Thus a search and examination of these multiple inventions clearly would involve an undue burden. While a search of the different inventions will substantially overlap, they will not be coextensive.

Applicants further argue that the MPEP 803.03 points out that in "most cases, up to ten independent and distinct **nucleotide** sequences will be examined in a single application without restriction" This argument is not persuasive, because as pointed out by applicants this application contains eight nucleotide sequences as well as their corresponding **amino acid** sequences at issue. Each of these nucleotide sequences encodes a different protein and each of the corresponding different proteins requires in addition to a search based on nucleotide and amino acid sequences, a text search based on other physical parameters of these independent and distinct proteins. For all of the above reasons applicants traversal of the restriction requirement is not found persuasive.

Priority

Applicants amendment of the first line of the specification to state that "this application is a divisional application of application Serial No. 09/330,611, filed June 11, 1999, which is a continuation-in-part of U.S. Patent Application Serial No. 09/182,942, filed November 24, 1998, now abandoned." is acknowledged.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the

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list may not be incorporated into the specification but must be submitted in a separate paper."

Applicants filing of information disclosures, Paper No. 3, filed 5/1/2001, is acknowledged. Those references considered have been initialed. It is noted that reference, R2 and R27 are missing the title, volume, number of the journal and date on the accompanying form 1449.

Specification

The disclosure is objected to because of the following informalities:

As discussed above, IDS references, R2 and R27 are missing the title, volume, number of the journal and date on the accompanying form 1449.

Appropriate correction is required.

Claim Objections

Claims 31, 36, 46 are objected to because of the following informalities:

Claims 31, 36 and 46 are dependent from rejected claims 30, 29, and 37 respectively.

Claims 31, 36 and 46 are further directed to non-elected subject matter.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39, 41 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 and 45 are indefinite in that each is confusing in that they are each drawn to the method of producing L- β -lysine of claims 30 and 37, respectively, wherein the a number of cofactors are required for lysine 2,3-aminomutase activity. As the presence of these cofactors is not a part of the claimed method, but rather the cofactors are required for lysine 2,3-aminomutase activity, their requirement for such activity is considered an inherent property of the lysine 2,3-aminomutase activity of the claimed method and thus claims 39 and 45 do not further limit claims 30 and 37. Therefore, claims 39 and 45 are identical to claims 30 and 37.

Claim 41 is indefinite in that it depends from the method of producing lysine 2,3-aminomutase of claim 37, and refers to "the immobilized lysine 2,3-aminomutase. Claim 37 which is dependent from claim 29 does not contain an immobilized lysine 2,3-aminomutase" and therefore there is no antecedent basis for "the immobilized lysine 2,3-aminomutase".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29, 30, 32, 37-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 29, 30, 32, 37-45 are directed to all possible methods of producing L- β -lysine comprising culturing any host cell comprising any expression vector that encodes any lysine 2, 3-aminomutase in the presence of L-lysine (claims 29, 37, 41, 42, 43, 44, 45), incubating L-lysine in the presence of any lysine 2, 3-aminomutase (claim 30, 32, 38, 39) or contacting L-lysine with any lysine 2, 3-aminomutase immobilized on a suitable support (claims 40).

The specification, however, only provides the representative species of the claimed methods comprising the use of the lysine 2,3-aminomutase enzymes of SEQ ID NOs: 2, 4, 6, 8, 10, 12, 14, and 16 and the DNAs which encode them, encompassed by these claims. There is no disclosure of any particular structure to function/activity relationship in the disclosed species. The specification fails to describe additional representative species of the enzymes, used by the methods, by any identifying structural characteristics or properties other than by their amino acid sequences and activity, for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

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Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard Hutson', followed by a long horizontal line extending to the right.

Richard Hutson, Ph.D.
Patent Examiner
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January 27, 2003